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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

October 5, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kevin Johnson, CEO
Mountain View Hospital
1000 East Highway #6
Payson, Utah 84651

Ref. # - DEN-00-02

PURGED

WARNING LETTER

Dear Mr. Johnson:

During an inspection of your blood bank facility in Mountain View Hospital that was conducted from May 21 through June 1, 1999, Consumer Safety Officer Kelly D. Moore documented the following violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680:

1. Blood Components and Plasma that were repeatedly reactive to a test for antibody to HIV were shipped without written approval from FDA [21 CFR 610.45(c)]. For example:
   a. Unit # was repeatedly reactive for anti-HIV 1/2 on 12/11/98 and reported western blot negative 12/22/98. The salvaged plasma from unit # was shipped on 12/31/98 to a plasma broker. The true status of the donor of unit # could not be known since no record demonstrated that the donor was tested in accordance with an acceptable re-entry protocol.
   b. Unit tested repeatedly reactive for HIV-1 antigen (P_{24}) on 9/23/98, but the red blood cell component from Unit # was released and consigned.

2. The Procedure, Revision Date 10-26-94, required donors who test repeatedly reactive for HTLV-1/2, HIV, HBsAg and HCV to be permanently deferred and the donors notified. Employees lacked adequate training because they were not following this procedure [21 CFR 606.20(b)]. The donor deferral files were not adequate to identify unsuitable donors so that products from such individuals would not be distributed [21 606.160(e)]. For example:

a. Donor [illegible] (unit # [illegible]) tested repeatedly reactive for HIV-1 antigen (P_{24}) in September 1998. A computer donor inquiry for the donor of Unit # [illegible] had the donor as "ACTIVE," but the donor was listed on the Permanent Donor Deferral File. Subsequently, this donor donated Unit # [illegible] on 1/26/99 and the red blood cell component was distributed on or about 1/30/99.

b. Donors [illegible] (unit # [illegible]), [illegible] (unit # [illegible]), [illegible] (unit # [illegible]), [illegible] (unit # [illegible]) and [illegible] (unit # [illegible]) tested repeatedly reactive for anti-HIV 1/2, but western blot negative in December 1998, May 1999, March 1999, March 1999, and November 1998, respectively. A computer donor inquiry listed these donors as "ACTIVE" (except the status of donor [illegible] was not determined) and the donors were not listed on the Permanent Donor Deferral File. No record(s) demonstrated that the donors were tested in accordance with an acceptable re-entry protocol.

c. Donors [illegible] (unit # [illegible]) and [illegible] (unit # [illegible]) tested repeatedly reactive for HBsAg, but confirmatory negative or indeterminate for HBsAg in March 1999 and November 1998, respectively. A computer donor inquiry listed these donors as "ACTIVE" and the donors were not listed on the Permanent Donor Deferral File. No record(s) demonstrated that the donors were tested in accordance with an acceptable re-entry protocol.

d. Donors [illegible] (unit # [illegible]) and [illegible] (unit # [illegible]) tested repeatedly reactive for anti-HTLV-1/2, but confirmatory negative in December 1998 and May 1998, respectively. A computer donor inquiry listed these donors as "ACTIVE" and the donors were not listed on the Permanent Donor Deferral File. No record(s) demonstrated that the donors were tested in accordance with an acceptable re-entry protocol.

e. Donors [illegible] (unit # [illegible]) and [illegible] (unit # [illegible]) tested repeatedly reactive for HCV, but RIBA negative in November 1998. A computer donor inquiry listed these donors as "ACTIVE" and the donors were not listed on the Permanent Donor Deferral File. No record(s) demonstrated that the donors were tested in accordance with an acceptable re-entry protocol.

f. Donors [illegible] (unit # [illegible]) tested repeatedly reactive for anti-HCV in March 1999 and [illegible] (unit # [illegible]) tested repeatedly reactive for HTLV-1 in May 1998. A computer donor inquiry listed these donors as "PERM DEF," but the donors were not listed on the Permanent Donor Deferral File.

g. Donors who tested repeatedly reactive, whose status remained "ACTIVE," as indicated in "a" through "f" above, were not notified.

3. The record from which unsuitable donors may be identified fails to maintain the confidentiality of donors [21 CFR 606.160(e)]. For example, the [illegible] procedure, Revision Date 10-26-94, indicated that "[illegible]."

However, the Permanent Donor Deferral File list indicated the test which was positive for each donor on the list. This list was accessible by donor aides for use in screening donors during mobile collections even though they had no need to know the test that was positive.

4. The procedure describing the criteria used to determine donor suitability, including acceptable medical history criteria, was not always followed [21 CFR 606.100(b)(1)] and donor selection records, including permanent and temporary deferrals for health reasons, were not always complete [606.160(b)(1)]. For example:

a. According to a procedure, an AABB Association Bulletin #95-8, "persons with a family history of Creutzfeldt-Jacob disease (CJD) be permanently deferred from donation." The medical history record for Donor [illegible] indicated that a relative had died of CJD; however, donor [illegible] donated unit [illegible] This unit was prepared into red blood cells and salvaged plasma that were released and consigned.

b. According to the procedure, [illegible], Revision Date: 012-17-97, donors who resided in the household and/or had sexual contact with an individual with viral hepatitis were deferred for at least 12 months. The donor questionnaire for donor [illegible] indicated she had close contact with a boyfriend with yellow jaundice, hepatitis, but did not document when. Unit [illegible] was collected and prepared into red blood cells and salvaged plasma that were released and consigned.

c. The donor questionnaire dated 2/24/99 for donor [illegible] indicated travel to China, the donor questionnaire dated 4/28/99 for donor [illegible] indicated travel to Honduras. The [illegible] procedure, Revised: 3/9/98, indicated that malaria was a problem in rural areas of China and that malaria and Chagas were a problem in rural areas of Honduras. The donor questionnaires for donor [illegible] and donor [illegible] did not indicate if travel was to rural areas. Units [illegible] and [illegible] were collected from the donors, respectively.

d. Donor Questionnaires were not checked for errors and omissions in a timely manner, in that, (1) [illegible] of [illegible] Donor Questionnaires reviewed found donors answering questions posed to both males and females and (2)Donor Questionnaires were observed that had not been reviewed for at least 30 days or longer.

e. A review of donor selection records found [illegible] out of [illegible] that showed donors [illegible] with pulse measurements outside the established specifications for acceptance, however, the donors were accepted.

f. A review of Donor Questionnaires found that [illegible] of [illegible] failed to include the lot number of the blood bag used during blood collection or the amount of blood collected.

5. Records of the periodic test of the capacity of shipping containers to maintain proper temperature in transit were not found for shipping containers used to transport blood from mobiles to the blood bank [21 606.160(b)(5)(iv)].

6. The procedure for [illegible], Revision Date 07-01-97, stated that "[illegible]" Regulations for Fresh Frozen Plasma require that "plasma shall be separated from the red blood cells, frozen solid within 6 hours after phlebotomy, and stored at -18C or colder." There is no assurance that Fresh Frozen Plasma was frozen within six (6) hours since validation/verification documentation for the [illegible]-fridge used for this purpose was not observed [21 CFR 640.34(b) and 606.60].

7. The periodic tests of the capacity of shipping containers to maintain proper temperature in transit did not take into account actual, worst case conditions of travel time and outside temperatures [21 CFR 606.160(b)(4)(iv)].

8. Processing and component worksheets, or other records, did not identify the person performing the separation of whole blood into packed red blood cells and plasma, the person labeling blood and blood components, or the person disposing of unsuitable blood products [21 CFR 606.160(a)(1)].

9. Blood Bank Disposition Records did not always document the disposition of plasma separated from homologous whole blood units [21 CFR 606.160(a)].

During a review of blood and blood component labeling, it was observed that the current ABO/Rh labels for labeling AB positive, AB negative, and B negative blood were not labeled "Non-Reactive for anti-HIV-2 and HIV-1 antigen". Therapeutic phlebotomy units were not labeled "Not For Transfusion." You should review all labels to assure they comply with applicable regulations.

Our office is in receipt of your response dated July 21, 1999 to the FDA-483 issued to your firm on June 1, 1999. You will receive with this letter additional correspondence with comments to your response.

This letter, as well as the Inspectional Observations, Form FDA-483, which was presented to and discussed with Dr. Stanley L. Gibbon, Medical Director, et al, at the close of the inspection is not intended to be an all inclusive list of deficiencies at your facility. Rather, they both represent unacceptable practices documented during our most recent inspection of your facility. It is your responsibility to insure that all requirements of the Act, and regulations promulgated thereunder, are being met.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated without further notice. These include license suspension, license revocation, seizure, and injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter regarding the specific steps you have taken to correct the above violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may reference corrective actions mentioned in your FDA-483 response of July 21, 1999, where applicable.

Your response should be sent to the Food and Drug Administration, Denver District Office, Attention: Russell W. Gripp, Compliance Officer, at the above address

Sincerely,

Gary C. Dean
Director, Denver District